

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : G01N		A2	(11) International Publication Number: WO 94/01749 (43) International Publication Date: 20 January 1994 (20.01.94)
(21) International Application Number: PCT/US93/06057 (22) International Filing Date: 24 June 1993 (24.06.93)		(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>	
(30) Priority data: 07/906,926 30 June 1992 (30.06.92) US			
(71) Applicant: ADVANCED HAEMOTECHNOLOGIES [US/US]; 2828 North Crescent Ridge Drive, The Woodlands, TX 77381 (US).			
(72) Inventor: MAYNARD, David, L. ; 18 Ridgeline Court, The Woodlands, TX 77381 (US).			
(74) Agents: SEELEY, David, O. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).			
(54) Title: APPARATUS AND METHODS FOR MONITORING HEMATOCRIT LEVELS OF BLOOD			
(57) Abstract <p>An apparatus and method are provided for measuring the hematocrit level of blood. The presently preferred embodiment comprises a light emitting device (14) which emits an amount of light into a blood sample (12). This light travels through the blood sample to two light detecting devices (18, 20) positioned relative to the light emitting device in a predetermined geometry such that light must travel farther to reach one of the light detecting devices than to reach the other. According to the present invention, the amount of light detected by one of the light detecting devices (18, 20) is regulated so that the amount of light detected is constant. Thereafter, the amount of light detected by the unregulated light detecting device is a linear representation of the hematocrit of the blood in the blood sample. The hematocrit sensor may be used to regulate the operating parameters of an autotransfusion system to maintain the hematocrit of the blood within a predetermined range.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

1 APPARATUS AND METHODS FOR MONITORING
HEMATOCRIT LEVELS OF BLOODBACKGROUND OF THE INVENTION5 1. Technical Field:

The present invention relates to apparatus and methods used in measuring and monitoring the hematocrit of blood. More specifically the present invention relates to apparatus and methods for measuring the hematocrit of blood 10 by differential geometry and using the hematocrit measuring apparatus to automatically control the parameters of an autotransfusion system.

15 2. Background Information:

Most surgical procedures result in some loss of blood from associated surgical incisions. Injured patients can often experience external and internal bleeding. If blood loss from injury or surgery is substantial, it becomes necessary to replenish lost blood through transfusion.

In many instances, it is possible to collect a patient's blood for use in replacing most or even all of the blood losses. It will be readily appreciated that blood collected from a wound or a surgical site will contain tissue fragments, lysed blood cells, and other 25 unwanted substances. Such blood must be treated for removal of unwanted substances before it is safe for reinfusion into the patient.

The general procedure of collecting a patient's blood, cleansing it, and then returning it to the patient is sometimes referred to as autotransfusion. Where autotransfusion is possible, it is a strongly preferred way of replacing a patient's blood losses. One reason that autotransfusion is so preferred is that it avoids incompatibility problems which sometimes can occur when 30 giving transfusions of blood obtained from someone other than the patient. Use of a patient's own blood to replace 35 blood losses has also become increasingly important in view

1 of issues relating to the safety of replacement blood, such
as the prevalence of acquired immune deficiency syndrome
(AIDS) or other diseases among blood donors in some
locales. Because of these benefits, and others,
5 autotransfusion is often the method of choice for
minimizing loss of cellular blood components during diverse
procedures ranging from surgery to plasma exchange therapy,
and is likely to become increasingly important in the
future.

10 The process of removing blood plasma and other
unwanted substances without any cleansing of the blood is
commonly referred to as plasmapheresis. Plasmapheresis has
long been practiced through use of filters having a pore
size large enough to pass plasma and other unwanted
15 substances found in the blood, such as anticoagulant,
toxins and components of lysed cells (which, for purposes
of brevity and simplicity, shall sometimes hereinafter be
referred to collectively as the "waste components" of
blood), but small enough to retain intact cells, such as
20 red blood cells, white blood cells and platelets (which
shall sometimes hereinafter be referred to collectively as
the "cellular components" of blood). Plasmapheresis has
also been practiced through use of a centrifuge to separate
plasma and other suspended waste components from the denser
25 cellular components, and then removing the plasma and
associated waste components.

Simple removal of plasma and associated waste
components is not adequate to remove all waste materials
associated with blood. It has been found that a more
30 thorough cleansing of blood can occur if the cellular
components are washed after the plasma is removed. United
States Patent No. 4,631,050 describes a process of
autotransfusion utilizing a membrane for filtration to
separate waste components from cellular components. That
35 patent describes an initial filtration to remove gross

1 debris, followed by addition of a washing solution to
reconstitute the blood, and then subjecting the
reconstituted mixture to another filtration step in order
to remove remaining waste components. United States
5 4,935,002 describes another autotransfusion apparatus for
collecting, processing, and returning blood to a patient
during or after surgery. The blood is filtered, washed,
and separated from gross particulate refuse.

During the processing of blood for autotransfusion, it
10 is desirable that the hematocrit of the processed blood be
maintained in an appropriate range in order to obtain a
thorough cleaning while minimizing problems such as
clogging the filtration apparatus, damage to the cells,
introducing excess solution into the patient, and the other
15 like problems. It is believed that an appropriate range is
from about 30% to 55%.

Differential geometry light transmission is a common
method for measuring hematocrit. Typically, a number of
20 emitters (especially from LEDs) and detectors are arranged
in a predetermined geometric relationship. Light of a
known value is emitted and the amount of light received
along a given path is measured. These measurements are
then applied mathematically to determine the desired
parameter.

25 Unfortunately, while much progress has been achieved
in this area, the full nature of light transmission and
diffusion through blood under all circumstances has not
been completely discovered, and thus is still unclear.
Therefore, the mathematical equations used by the devices
30 and methods today are based upon empirical observation by
the users of what appears to work well. Consequently, such
equations tend to be extremely complicated and require
micro-computers to be implemented.

35 Additionally, after passing through the blood, the
light signals received are highly non-linear before

1 conversion, and so require high accuracy Analog/Digital
converters, electrical devices used for converting analog
signals to discrete digital signals, in order to analyze
the wide dynamic range of values encountered by the light
5 detectors.

Further, in the devices used today, it is difficult to precisely control the amount of light actually emitted, especially since the intensity of light output versus drive current degrades as an LED ages.

10 With regard to the plasma and waste separators in use today, there is no way of continuously measuring the hematocrit of the blood during processing so that the parameters of the processing system can be adjusted to compensate for hematocrit readings outside of a desired
15 range. Therefore, the plasma and waste separators cannot be operated at their optimum levels.

SUMMARY OF THE INVENTION

20 In accordance with the invention as embodied and broadly described herein, a hematocrit sensor apparatus is provided which is capable of measuring the hematocrit level of blood in a simple, uncomplicated manner.

25 More specifically, the present invention provides an apparatus and method for measuring the hematocrit level of blood which has been cleansed and processed for reinfusion into a patient by a plasma separator apparatus. The hematocrit sensor operates to continuously monitor the hematocrit level of the processed blood so that the hematocrit can be kept within a prescribed range. When the
30 level gets too low, a microprocessor adjusts the parameter of the plasma separator apparatus in order to compensate for the low hematocrit level.

35 The presently preferred embodiment is a hematocrit measurement sensor comprising a light emitting device for emitting light into a blood sample and two light detecting

1 devices for detecting the light emitted into the blood
sample. The light emitting and light detecting devices are
arranged in a predetermined geometric pattern such that
light traveling from the light emitting device must travel
5 further to reach one light detecting device than to reach
the other light detecting device, thereby forming a light
path from the light emitting device to one light detecting
device which is longer than the light path from the light
emitting device to the other light detecting device. The
10 term "path" can be considered to mean generally a straight
line path. However, it should be noted that there will be
some amount of light scattering as the light passes through
the blood. Therefore, the "path" is a composite of the
15 light passing from the light emitting device to the light
detecting device.

According to the present invention, the amount of
light being received by one of the light detecting devices
is regulated to be a constant value. This regulation
occurs through a feedback circuit wherein the light
20 received by one of the light detecting devices is sent
through the feedback circuit to a regulation circuit which
compares the received light to a constant reference source
and adjusts the drive current to the light emitting device
so that the value received by the regulated light detecting
25 device matches the reference value, thereby also regulating
the output of the light emitting device.

When one of the light detecting devices is regulated
in this way, the output of the remaining light detecting
device takes on an inherently linear representation of
30 hematocrit. No complicated equations are necessary to
transform the data generated by the light detecting device
into a value for a hematocrit measurement.

Calibration then converts the already linear
representation into more familiar and readable units.

1 The hematocrit sensor of the present invention is
especially useful in combination with a plasma and waste
separator system such as, for example, that used in an
autotransfusion system. Although many different plasma and
5 waste separator systems may be combined with the hematocrit
sensor, the present discussion will mainly describe one
system in particular. In this particular system, the
hematocrit sensor is attached to the plasma separator
system at the output area where the processed blood is
10 ready to be reinfused into a patient. A microprocessor may
be used to connect the hematocrit sensor to the operations
of the plasma separator apparatus. Limit switches may also
be used.

15 The hematocrit sensor continuously monitors the
hematocrit level of the processed blood. If the hematocrit
level falls out of a certain range (here a preferred range
is about 45-55%), an algorithm programmed into the
microprocessor automatically adjusts the parameters of the
plasma separator apparatus to compensate for the too high
20 or too low hematocrit. For example, if the hematocrit
level is too low, the microprocessor may, as one option,
automatically adjust the rotor speed of the plasma
separator in order to increase agitation of the blood and
separation of plasma and waste from the blood. If the
25 hematocrit level is too high, a separate action will be
automatically taken to compensate for the high level.
Through this process, the blood being reinfused into a
patient will always have an appropriate hematocrit level.

30 BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, which represent the best mode presently contemplated for carrying out the present invention:

35 Figure 1 is a perspective view of one embodiment of
the present invention representative of "through" geometry.

1 Figure 2 is a schematic representation of "through" geometry.

 Figure 3 is a graph of linearity found using the "through" geometry before calibration.

5 Figure 4 is a graph of linearity found using the "through" geometry after calibration.

 Figure 5 is a perspective view of the preferred embodiment of the present invention representative of "back-scatter" geometry.

10 Figure 6 is a schematic representation of "back-scatter" geometry.

 Figure 7 is a graph of linearity found using the "back-scatter" geometry.

15 Figure 8 is a perspective view of an autotransfusion system wherein a hematocrit sensor is attached.

 Figure 9 is a perspective view of an optical connector within the scope of the present invention which provides a window between the flow of blood and the light emitting and light detecting devices.

20 Figure 10 is a cross-section view of the optical connector of Figure 9.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

25 The present invention is directed to a hematocrit sensor apparatus and method for measuring the hematocrit level of blood. The hematocrit sensor is especially useful in combination with a plasma separator apparatus wherein blood is processed for use in autotransfusion. However, it should also be appreciated that the teachings herein will 30 be readily transferable to other applications involving the measurement of the hematocrit level of blood.

 Reference is first made to Figure 1, which illustrates one embodiment of the hematocrit sensor apparatus of the present invention. In Figure 1, the hematocrit sensor, 35 identified generally by reference numeral 10, is positioned

1 beside a blood sample 12. The blood sample 12 is typically
held in a plastic material forming an extracorporeal
circuit through which blood is passed. The hematocrit
sensor 10 is configured such that the hematocrit level of
5 a flowing bloodstream can be measured by emitting light
from one side of the blood stream, through the blood, and
to light detectors on the other side of the blood stream.
This embodiment is referred to as "through" geometry.

A light emitting means for emitting light into a blood
10 sample is positioned on one side of the blood sample. It
should be noted that the best results occur when the
thickness of the blood sample is around one millimeter. In
Figure 1, the light emitting means is illustrated as an
infrared light emitting diode 14 (hereinafter "LED"). In
15 the preferred embodiment, the LED 14 emits light at 805
nanometers. However, the light emitting means within the
scope of the invention may comprise any infrared diode, or
any device that emits light in the infrared range, such as
a laser.

20 Positioned across the blood sample from LED 14 are a
first light detecting means for detecting light emitted
from the light emitting means and a second light detecting
means for detecting light emitted from the light emitting
means. The first light detecting means is positioned to
25 receive light emitted from the light emitting means into
the blood sample along a first path to the first light
detecting means. Signals put out by the first light
detecting means corresponds to the amount of light
detected.

30 The second light detecting means is positioned to
receive light emitted from the light emitting means into
the blood sample such that light emitted from the light
emitting means must travel farther to reach the second
light detecting means than to reach the first light
35 detecting means, thereby forming a second path from the

1 light emitting means to the second light detecting means which is longer than the first path from the light emitting means to the first light detecting means. Signals put out by the second light detecting means correspond to the
5 amount of light detected.

In Figure 1, these light detecting means are illustrated by a first diode 18 and a second diode 20. First diode 18 and second diode 20 are positioned to detect light emitted from LED 14 into the blood sample. Signals
10 thereafter output by the first diode 18 and the second diode 20 correspond to the amount of light detected. Although in the preferred embodiment PIN diodes are used, any quality photodetector would be sufficient for use as the light detecting means.

15 In the present invention, positioning of the first and second diodes, 18 and 20, and the LED 14, is important to create the "through" geometry. LED 14 is positioned such that the path of light from LED 14 through blood sample 12 and to first diode 18 is shorter than the path of light
20 from LED 14 through blood sample 12 and to second diode 20. Thus, by specific positioning of LED 14 and first and second diodes, 18 and 20, there is formed a short first path and a long second path.

It should be noted that correct positioning of the
25 devices may vary with respect to distances between LED 14 and first and second diodes, 18 and 20. In the preferred embodiment, the long second path is two millimeters and the short first path is one millimeter. It has also been found successful, for example, to have a long second path two and
30 one half millimeters and a short first path one millimeter, or to have a long second path three millimeters, and a short first path two millimeters. It appears that it is the difference in the path lengths and not particularly the magnitude of that difference that is important to the
35 present invention. The path lengths may be adjusted.

1 However, it is important to note that the farther away the
detectors are placed from the emitters, the more power
would be needed for the emitters to emit an amount of light
which will reach the detectors.

5 Although it can be appreciated that many alternate
configurations are available, one preferred configuration
for forming this "through" geometry embodiment is to place
first and second diodes, 18 and 20, beside each other on
one side of the blood sample. LED 14 is then placed on the
10 opposite side of the blood sample along a center line
between the two diodes, and then offset longitudinally
toward one diode and away from the other. The side to
which LED 14 is offset forms the short first path, and the
15 remaining side forms the long second path. In Figure 1,
the path to first diode 18 is the short first path, while
the path to second diode 20 is the long second path.

As discussed, light emitted from LED 14 through the
blood sample is detected by first diode 18 and second
diode 20. According to the present invention, it is
20 necessary to regulate the amount of light detected on one
path so that the amount detected remains a constant. The
device within the scope of the present invention further
comprises regulating means for regulating the intensity of
light emitted by the light emitting means such that the
25 received light on one of the paths remains at a constant
value.

Another feature of the present invention are
amplifying means for performing offset and gain calibration
of the signals output from the light detecting means. An
30 amplification signal is provided which is a linear
representation of the hematocrit of blood in the blood
sample. Within the scope of the present invention, one
amplifying means is an offset and gain calibration
amplifier.

1 In the "through" geometry, the amount of light
detected on the short first path is regulated by
electrically connecting first diode 18 to LED 14 through a
feedback circuit. This feedback circuit is illustrated in
5 Figure 2 and generally labeled 22. When LED 14 is
energized, light is emitted into the blood. The light
received by the first diode 18 is amplified and sent
through feedback circuit 22 to a regulation circuit 24. At
the regulation circuit 24, the received light is compared
10 to a constant reference source 26, and the drive current to
the light emitting device is adjusted so that the value
received by first diode 18 matches the value of the
reference source 26, thereby regulating the output of the
light emitting device and ensuring that the amount of light
15 received by the first diode 14 remains at a constant value.

Once light received on the short first path is
regulated, the amount of light received on the long path is
then analyzed. Second diode 20 of the long second path
outputs a signal corresponding to the amount of light it
receives. The resulting output has been found to provide
a linear representation of hematocrit. Additionally, it
has been found that the output signal of this second
diode 20 decreases as the hematocrit rises. This light is
amplified and then fed to a standard "offset and gain"
25 calibration amplifier known in the art and labelled
generally in Figure 2 as 28.

It is important to note that in devices in use today
where hematocrit is measured by light detecting diodes
which detect light emitted into the blood from light
30 emitting diodes, the output signals of the light detecting
diodes cannot be easily analyzed. Complex equations must
be used in order to analyze and form the data into a linear
hematocrit reading. Microprocessors and A/D converters are
necessary to obtain the hematocrit measurements.

1 In contrast, with the embodiment of the present invention, when the amount of light traveling on one path is regulated, the output from the unregulated path, without the need of complex mathematical process, forms a linear
5 hematocrit reading. Figure 3 illustrates the linearity of the output from the "through" geometry.

10 Calibration of the output then converts the already linear representation into more familiar and readable units. Figure 4 illustrates the linearity of the output from the "through" geometry after calibration.

15 Although the "through" geometry is successful and demonstrates the practicality of the present invention, there are some limitations to the embodiment. For example, blood is a relatively dense optical medium. Therefore, the
20 blood flow channels which are used with the "through" geometry must be very narrow in order to allow adequate light levels to penetrate. This can be undesirable due to the nature of the extracorporeal flow rates expected. A narrow flow channel was too confining.

25 Therefore, a second and preferred embodiment was developed. This embodiment, illustrated in Figure 5 comprises a "back-scatter" geometry. Here, an LED 30 is positioned on the same side of the blood sample as the light detecting means, as opposed to being positioned on
30 the opposite side as with the "through" geometry. The light detecting means are illustrated in Figure 4 as a short path diode 32 and a long path diode 34. Again, the path to diode 34 is longer than the path to diode 32. As the light emitted into the blood stream does not have to fully penetrate the blood stream for detection by the light detecting means to occur, the thickness of the blood flow channel is not at issue. It is important to note that the back-scatter path is not a simple path. The back-scattered light detected is not simply one path of light, but more of
35 an aggregation of light reflected back through the blood.

1 Figure 4 presents a simplified illustration of a back-scattered light path.

5 In the "back-scatter" geometry, the long second path is regulated so that the amount of light detected remains at a constant value. (Recall that in the "through" geometry, the short first path is regulated.) The long path diode 34 is electronically connected to LED 30 by a feedback circuit, illustrated in Figure 6 and labelled generally as 42. The amount of light detected by long path diode 34 is amplified and fed to a regulation circuit 44. This circuit then compares the light received by the long path diode 34 to a constant reference source 46 and adjusts the drive current to LED 30 so that the value received on the long second path matches the value of constant 15 reference source 46. As with the "through" geometry, this holds constant the amount of light received by one path.

20 The signal is then fed to a standard "offset and gain" calibration amplifier 48. The resulting output is the linear hematocrit representation. In the back-scatter geometry, as the hematocrit rises, the output signal of the short first path increases. By contrast, it should be noted that in the "through" geometry, the situation is reverse. There, as the hematocrit rises, the output signal of the long second path decreases.

25 Figure 6 illustrates the linearity of the output signals of the "back-scatter" geometry. As can be seen from the graph of Figure 7, with the device of the present invention, complex computer manipulations are again not necessary to form the output signals into a linear hematocrit reading. Calibration, however, converts the signals into more familiar and usable terms. Figure 7 illustrates the calibrated output signals.

30 It is within the scope of the present invention for the light emitting diode and the light detecting diodes to be arranged either directly against the blood sample

1 itself, or separated from the bloodstream by a clear
window. Although it has been found that better results are
obtained when a window is not used, it is more practical to
use a window to separate the blood from the diodes. One
5 reason for this is the expense of the diodes. Without an
isolating window, the diodes would be in direct contact
with the blood and would have to be constantly replaced due
to contamination. Another reason is that most applications
10 of the hematocrit sensor will be in extracorporeal
circuits, where the clear window may already be present.
Figures 1 and 4 illustrate use of a window 52 separating
the diodes from the blood stream 12.

It is also within the scope of the present invention
15 to employ conveying means, in communication with the light
emitting means and the light detecting means, for
transmitting light from the light emitting means to the
blood and to the light detecting means along first and
second paths. The first conveying means is in
20 communication with the first light emitting means and
transmits light from the light emitting means to the blood.
The second conveying means is in communication with the
first light detecting means and transmits light to the
first light detecting means through the blood along the
25 first path. The third conveying means is in communication
with the second light detecting means and transmits light
to the second light detecting means through the blood along
the second path. The preferred conveying means is
illustrated in Figure 5 as first, second, and third plastic
30 fibers, 54, 56, and 58 respectively. It should be
appreciated that glass fibers may also be used within the
scope of the present invention.

In the preferred embodiment, one millimeter diameter
fibers are placed sided by side next to a blood sample.
The light emitting means and the light detecting means are
35 placed on the outer ends of the fibers, and the free ends

1 of the fibers are then placed against the window of the
blood stream. As these fibers are one millimeter in
diameter, the measurement taken center to center would be
two millimeters to the long second path versus one
5 millimeter to the short first path.

In Figure 5, LED 30 is illustrated as positioned
against the end of first fiber 54. Short path diode 32 is
positioned against the end of second fiber 56. Long path
diode 34 is positioned against the end of third fiber 58.
10 Although the preferred embodiment employs the use of
plastic fibers, glass fibers or no fibers at all, may also
be used.

For example, Figure 1 illustrates the first diode 18
and second diode 20 directly against the window 38 of blood
15 stream 12. However, it is possible to add glass or plastic
fibers to the embodiment and the embodiment would still
perform within the scope of the present invention.

Further, the hematocrit measuring device of the
present invention also effectively operates when the light
20 source is pulsed. Pulsing neither adds to nor detracts
from the methodology described.

A novel method for measuring the hematocrit of blood
using the hematocrit sensor of the present invention is
also disclosed. The first step of the novel method
25 comprises positioning a light emitting device so as to emit
light into a blood sample. The second step is to energize
the light emitting device such that light is emitted
through the blood sample.

Next, a first light detecting device is positioned
30 such that it receives light emitted from the light emitting
device into the blood along a first path, and a second
light detecting device alongside the blood sample such that
it also receives light emitted from the light emitting
device into the blood. The light emitting device, the
35 first light detecting device and the second light detecting

1 device are all positioned in a predetermined geometric
relationship, whereby the second path is longer than the
first path.

5 A feedback circuit is then provided for monitoring the
second light detecting device, and regulating the amount of
light received by the second light detecting device so that
it remains at a constant value. This amount of light may
be amplified and sent through the feedback circuit to a
regulation circuit where it is compared to a constant
10 reference source. The drive current to the light emitting
device is then automatically adjusted so that the value of
the amount of light received by the second light detecting
device matches the reference value. This thereby also
regulates the amount of light emitted by the light emitting
15 device.

The final step comprises amplifying the light received
by the first light detecting device and feeding the
amplified light to a standard offset and gain calibration
20 amplifier in order to generate an output signal of the
first light detecting device which will be a linear
representation in familiar units of the hematocrit of blood
in the blood sample. By this novel method, a linear
hematocrit reading is obtained without the need for complex
25 equations processed by a microcomputer.

Another important aspect of the hematocrit sensor of
the present invention is its possible use with a plasma
separator apparatus such as used in an autotransfusion
system. Typical autotransfusion systems in the prior art
do not have the capability to constantly monitor and
30 maintain the hematocrit levels of the blood as they process
the blood for reinfusion into a patient.

Use of the novel hematocrit sensor with a plasma
separator apparatus of an autotransfusion system will be
described below, with reference to Figure 8. Having the
35 hematocrit sensor 10 attached to the autotransfusion system

1 of Figure 8, identified generally by reference numeral 66, allows automatic monitoring and adjustment of the autotransfusion system. It should be realized that although a particular autotransfusion system is herein
5 described, use of the device of the present invention is not limited to this particular autotransfusion system. Any comparable plasma separator system may be used.

Autotransfusion system 66 is configured for use in recovering blood from a surgical site, so that the blood
10 can be cleaned and returned to the patient. A sucker 68 is used to aspirate blood from a surgical site. A source of anticoagulant 70 is coupled to sucker 68 so that mixing of anticoagulant occurs quickly, thereby minimizing formation of blood clots. Aspirated blood and anticoagulant are
15 drawn into a conventional blood collection reservoir 72, which includes a filter 74 having a pore size which will remove large particles such as blood clots, pieces of tissue, orthopedic cement, and the like, but which will pass cellular components of blood. Blood collection
20 reservoir 72 also serves to effect defoaming of blood collected therein.

A roller pump 76 is advantageously used to pump blood from collection reservoir 72 into a plasma separator, depicted generally by reference numeral 80. A wash
25 solution, preferably saline, is also pumped into plasma separator 80 from a source 82. The wash solution is mixed with partially cleansed blood by rotors (not shown) within the plasma separator 80 in order to effect more thorough separation of waste components from the cellular components
30 of the blood being processed by the plasma separator. Cleansed blood processed by plasma separator 80 is collected in a blood collection bag 86, and from there it is returned to the patient, typically by conventional gravity infusion. Plasma, anticoagulant, and other waste
35 components of the blood are collected in a waste collection

1 bag 88, which may be discarded. A presently preferred
plasma separator is described in United States Patent
Application Serial No. 07/844,232, filed March 2, 1992,
which is hereby incorporated by reference.

5 Before blood is collected in blood collection bag 86,
it passes through the area where the hematocrit sensor 10
is located. As can be seen in Figure 8, the hematocrit
sensor 10 is positioned within the sensor head 90 between
the outlet of the plasma separator 80 and the blood
10 collection bag 86. Not only is hematocrit sensor 10
physically connected to autotransfusion system 66, but it
may also be electronically connected by means of a
microprocessor which controls the operating parameters of
the autotransfusion system.

15 After the blood is processed by the system, the blood
flows past the hematocrit sensor where the hematocrit level
of the blood is measured. If the hematocrit level falls
out of a certain range, (again, the preferred range here
being about 45-55%), an algorithm programmed into the
20 microprocessor will automatically adjust at least one
parameter of the plasma separator apparatus so as to
compensate for the too high or too low hematocrit. For
example, if the hematocrit level is too low, the
microprocessor may, as one option, automatically adjust the
25 speed of rotors within the plasma separator in order to
increase agitation of the blood, and separation of plasma
and waste from the blood. Another option may be to
decrease the rate of pumping blood into the system. With
less blood flowing through, performance of the system can
30 increase. Alternatively, if the hematocrit level is too
high, a separate action can be automatically taken to
compensate for the high level.

Thus, it can be seen that through this process, the
blood being reinfused into a patient will always have an
35 appropriate hematocrit level.

1 It is conceivable that many different algorithms may
be programmed into the microprocessor so that a variety of
actions will be available to compensate for either a low or
high hematocrit level. Additionally, the microprocessor
5 may also be programmed so that if the hematocrit level
falls to an unacceptable and uncorrectable level, the
system will automatically stop, and an alarm sound so as to
alert an operator to examine the system.

10 This programming ability is an advantage over
conventional systems. In conventional systems, there is no
way of measuring and automatically controlling the
hematocrit level of blood should it be found to be too high
or low. An operator must always measure the hematocrit
separately, and then must make any needed adjustments
15 manually. Constant supervision is necessary.

20 With the hematocrit sensor of the present invention,
however, the hematocrit level of the blood is constantly
monitored, and any necessary adjustments to the
autotransfusion system automatically takes place by means
of the microprocessor linking the hematocrit sensor and the
autotransfusion system. Only when the microprocessor
cannot adjust the system enough to correct the too high or
low hematocrit, will an operator have to step in and solve
the problem.

25 A further novel aspect of the present invention is an
optical connector used with the hematocrit sensor to
separate the components of the hematocrit sensor from
direct contact with the blood. The optical connector is
illustrated in Figures 9 and 10 and labelled 100. Optical
30 connector 100 is comprised of a generally hollow member 102
adapted to receive a blood sample therein with respect to
which hematocrit is to be measured. An optically clear
flexible optical window 106 is positioned on the generally
hollow member 102. Through optical window 106, the blood
35 sample within the generally hollow member 102 may be

1 visually accessed for measurement of its hematocrit. A support 110 for securing the optical fibers to the generally hollow member may extend from the flexible optical window 106 substantially perpendicularly from the
5 generally hollow member 102. As seen in Figures 9 and 10, fibers 54, 56 and 58 are secured within support 110 against flexible optical window 106.

Optical window 106 should be completely free of optical defects. The presently preferred material for
10 optical window 106 is a PVC resin. However, any material which is flexible and provides optical clarity is within the scope of the present invention.

As can be seen in Figure 9, optical connector 100 is placed within the sensor head 90 of hematocrit sensor 10,
15 and the generally hollow member 102 is connected to a blood flow channel 114. As the generally hollow member 102 is connected to blood flow channel 114, flexible optical window 106 is positioned over fibers 54, 56, and 58. By this positioning of the flexible optical window tube 102
20 over fibers 54, 56, and 58, flexible optical window 106 is pressed against fibers 54, 56, and 58. As optical window 106 is flexible, it forms around and presses firmly against the fibers, thus securing the fibers firmly in place so as to provide visual access to the blood sample
25 while protecting the fibers from direct contact with the blood. With use of the optical connector 100, the fibers never directly contact the blood, and so do not have to be replaced with each use.

When fibers 54, 56 and 58 are pressed against flexible
30 optical window 106, flexible optical window 106 conforms its shape to the ends of the fibers so that the flexible optical window 106 rests against fibers 54, 56 and 58 tightly. Generally, because of tolerances, it is difficult to align fibers 54, 56 and 58 so that the end of each fiber
35 terminates against the optical window. To compensate for

1 this tolerance variation, flexible optical window 106 is
flexible enough so that the fibers will mate tightly with
the optical window and allow detection of the blood sample
through the flexible optical window 106 while preventing
5 contact between the blood and the detectors.

In one embodiment, once the fibers are positioned into support 110, they are glued into place.

10 Optical connector 100 is a disposable component of the hematocrit sensor system. Once used, it may be removed from sensor head 90 and thrown away. Although it is substantially cylindrical in the preferred embodiment, other shapes are also within the scope of the present invention.

15 In Figure 9, it can be seen that optical connector 100 lies inside of sensor head 90. Sensor head 90 is comprised of a lid 120 and a bottom half 124 connected on one side by a hinge 126. When lid 120 of sensor head 90 is opened, optical connector 100 may be placed inside. A locking arm 122 used to allow access to the inside of sensor
20 head 90 by engaging lid 120 to bottom half 124, or disengaging lid 120 from bottom half 124, is connected to bottom half 124 of sensor head 90. Locking arm 122 pivots upwards around its point of connection with bottom half 124 of sensor head 90 and engages with lid 120, thus securing
25 lid 120 to bottom half 124 and thereby placing sensor head 90 into a closed position. When locking arm 122 is pivoted downward, it disengages with lid 120, and allows lid 120 to be lifted, thereby placing sensor head 90 into an opened position wherein optical connector 100 can be
30 placed inside, or withdrawn.

Another important aspect of the present invention which is disclosed herein is the novel method for automatically controlling the operation of an autotransfusion system by using hematocrit measurement to control parameters of a plasma separator apparatus. The
35

1 first step of this method comprises attaching a
hematocrit sensor to a plasma separator apparatus wherein
cellular components of blood, red blood cells, white blood
cells, and platelets, are separated from such waste
5 components as plasma, anticoagulant, toxins, and other
relatively small molecules. Once attached, the hematocrit
sensor can then constantly monitor the hematocrit level in
the blood during operation of the separator apparatus, so
that the operation of the separator apparatus can be
10 adjusted in order to keep the hematocrit level within a
desired range... Thus, with the hematocrit sensor of the
present invention, the operator of a plasma separator
apparatus can know when adjustments to the operating
parameters of the plasma separator device are necessary in
15 order to obtain high quality blood, and can take action
immediately after being notified by readings of the
hematocrit sensor.

The hematocrit sensor of the present invention may be used with many different types of autotransfusion systems.
20 In one particular system, however, blood is pumped through a plasma separator apparatus, where rotating means within the apparatus for producing movement of cellular components of blood causes turbulence. This thereby increases the filtration of waste components. Through readings from the
25 hematocrit sensor of the present invention, the operator of the plasma separator apparatus would be able to know whether the speed of the rotor means should be increased or decreased in order to obtain the right amount of filtration necessary to produce a hematocrit level within a desired range.

It can be appreciated that the hematocrit sensor may not only be physically coupled with the autotransfusion system, but it may also be electronically joined to the plasma separator apparatus of the autotransfusion system.
35 One possible way would be through connection by a

1 microprocessor. The microprocessor could function to
process measurements obtained by the hematocrit sensor. If
the measurements do not fall within a predetermined
acceptable range, the microprocessor can then automatically
5 adjust at least one operating parameter of the plasma
separator apparatus in order to bring the hematocrit back
to the desired range. Various algorithms can be programmed
into the microprocessor such that each hematocrit reading
automatically produces a different and appropriate response
10 from the plasma separator apparatus.

Other ways for the hematocrit sensor to be
electronically linked to the plasma separator apparatus are
by using discrete circuitry, or by using a limit switch.
The regulation circuit of the present invention can be used
15 to hold the motor of the apparatus constant. The inherent
linearity of the signal outputs of the present device is
used to control the circuits and switches.

It will be readily appreciated that the hematocrit
sensor of the present invention may be used with many types
20 of different systems, as well as with other apparatus such
as heart and lung machines.

It should also be noted that one use of the hematocrit
sensor may be to detect air in the blood. If the
hematocrit is low, during conditions when there should be
25 large quantity of blood cells, it may be deduced that air
is present and the machine can be stopped. This capability
can be useful, for example, when the blood is in a bag
which is gravity connected to a patient. It is important
not to force air into the patient.

30 Further, the hematocrit sensor may be used with
autotransfusion system to indicate the beginning or end
of each autotransfusion cycle. If the hematocrit
measurement of blood before and after being processed by
35 the autotransfusion system is known, then by monitoring
hematocrit measurements as registered by the hematocrit

1 sensor, an operator could identify the beginning and end of
each cleansing cycle.

5 The present invention may be embodied in other
specific forms without departing from its spirit or
essential characteristics. The described embodiments are
to be considered in all respects only as illustrative and
not restrictive, and the scope of the invention is
indicated by the appended claims rather than by the
foregoing description. All changes which come within the
10 meaning and range of equivalency of the claims are to be
embraced within their scope.

What is claimed is:

15

20

25

30

35

1 1. An apparatus for measuring the hematocrit of blood comprising:

 light emitting means for emitting light into a blood sample;

5 first light detecting means for detecting light emitted from the light emitting means, said first light detecting means positioned to receive light emitted from the light emitting means into the blood sample along a first path to the first light detecting means, the first light detecting means outputting a signal corresponding to the amount of light detected;

10 second light detecting means for detecting light emitted from the light emitting means, said second light detecting means being positioned to receive light emitted from the light emitting means into the blood sample, such that light emitted from the light emitting means must travel farther to reach the second light detecting means than to reach the first light detecting means, thereby forming a second path from the light emitting means to the second light detecting means which is longer than the first path from the light emitting means to the first light detecting means, the second light detecting means outputting a signal corresponding to the amount of light detected;

15 20 and

25 regulating means for regulating the intensity of light emitted by the light emitting means such that the received light on one of the paths remains at a constant value.

30 35 2. An apparatus for measuring the hematocrit of blood as defined in claim 1, wherein the light emitting means comprises an infrared light emitting diode.

1 3. An apparatus for measuring the hematocrit of blood as defined in claim 1, wherein the light emitting means comprises an infrared laser.

5 4. An apparatus for measuring the hematocrit of blood as defined in claim 2, wherein the infrared light emitting diode emits light at approximately 805 nanometers.

10 5. An apparatus for measuring the hematocrit of blood as defined in claim 1, wherein at least one of the light detecting means comprises a PIN diode.

15 6. An apparatus for measuring the hematocrit of blood as defined in claim 1, further comprising amplifying means for providing an amplified signal which is a linear representation of the hematocrit of blood in the blood sample.

20 7. An apparatus for measuring the hematocrit of blood as defined in claim 1, wherein at least one of the light detecting means comprises a photodetector.

25 8. An apparatus for measuring the hematocrit of blood as defined in claim 1, further comprising:

first conveying means, in communication with the light emitting means, for transmitting light from the light emitting means to the blood;

30 second conveying means, in communication with the first light detecting means, for transmitting light passing through the blood to the first light detecting means along the first path; and

third conveying means, in communication with the second light detecting means, for transmitting light

1 passing through the blood to the second light detecting means along the second path.

5 9. An apparatus for measuring the hematocrit of blood as defined in claim 8, wherein the conveying means comprises glass fibers.

10 10. An apparatus for measuring the hematocrit of blood as defined in claim 8, wherein the conveying means comprises plastic fibers.

15 11. An apparatus for measuring the hematocrit of blood as defined in claim 1, further comprising an optical connector, said optical connector comprising a generally hollow member adapted to receive therein the blood sample with respect to which hematocrit is to be measured, and an optically clear flexible optical window positioned on the generally hollow member through which blood can be monitored.

20 12. An apparatus for measuring the hematocrit of blood as defined in claim 11, further comprising a support extending from the flexible optical window substantially perpendicularly from the cylindrical member, for securing 25 to the cylindrical member the light emitting and light detecting means, thereby allowing the light emitting and light detecting means access to the blood sample without direct contact with the blood sample.

30 13. An apparatus for measuring the hematocrit of blood as defined in claim 11, wherein the flexible optical window comprises a polyvinylchloride resin material.

1 14. An apparatus for measuring the hematocrit of
blood as defined in claim 11, wherein the flexible optical
window comprises an optically clear material.

5 15. An apparatus for measuring the hematocrit of
blood comprising:

 light emitting means for emitting light into a
blood sample;

10 first light detecting means for detecting light
emitted from the light emitting means, said first
light detecting means positioned to receive light
emitted from the light emitting means into the blood
sample along a first path to the first light detecting
means, said first light detecting means outputting a
15 signal corresponding to the amount of light detected;

 second light detecting means for detecting light
emitted from the light emitting means, said second
light detecting means being positioned to receive
light emitted from the light emitting means into the
blood sample, such that light emitted from the light
emitting means must travel farther to reach the second
light detecting means than to reach the first light
detecting means, thereby forming a second path from
the light emitting means to the second light detecting
25 means which is longer than the first path from the
light emitting means to the first light detecting
means, the second light detecting means outputting a
signal corresponding to the amount of light detected;

30 first conveying means, in communication with the
light emitting means, for transmitting light from the
light emitting means to the blood;

 second conveying means, in communication with the
near detecting means, for transmitting to the first
light detecting means light passing through the blood
35 along the first path;

1 third conveying means, in communication with the far detecting means, for transmitting to the second light detecting means light passing through the blood along the second path; and

5 regulating means for regulating the intensity of light emitted by the light emitting means such that the received light on one of the paths remains at a constant value.

10 16. An apparatus for measuring the hematocrit of blood as defined in claim 15, wherein the light emitting means comprises an infrared light emitting diode.

15 17. An apparatus for measuring the hematocrit of blood as defined in claim 15, wherein the light detecting means comprises a photodiode.

20 18. An apparatus for measuring the hematocrit of blood as defined in claim 15, wherein the conveying means comprises glass fibers.

25 19. An apparatus for measuring the hematocrit of blood as defined in claim 15, wherein the conveying means comprises plastic fibers.

20 20. An apparatus for measuring the hematocrit of blood as defined in claim 15, further comprising amplifying means for performing offset and gain calibration of the signals output from the first and second light detecting means so as to provide an amplification signal which is a linear representation of the hematocrit of blood in the blood sample.

30 21. A method for measuring the hematocrit of blood comprising the steps of:

- 1 (a) positioning a light emitting device so as to emit light through a blood sample;
- 5 (b) energizing the light emitting device such that light is emitted through the blood sample;
- 10 (c) positioning a first light detecting device such that it receives light emitted from the light emitting device through the blood sample along a first path;
- 15 (d) positioning a second light detecting device such that it receives light emitted from the light emitting device through the blood sample along a second path, whereby the second path is longer than the first path;
- 20 (e) providing a feedback circuit for monitoring the light detected by the second light detecting device;
- 25 (f) regulating the intensity of light emitted by the light emitting device so that the amount of light detected by the second light detecting device remains at a constant value; and
- 30 (g) detecting the amount of light received by the first light detecting device.

22. A method for measuring the hematocrit of blood as defined in claim 21, further comprising the step of providing an amplifier which receives and converts input signals from the light detecting devices, so as to generate an amplified output signal which is a linear representation of the hematocrit of blood in the blood sample.

- 30
23. A method for measuring the hematocrit of blood comprising the steps of:
 - (a) positioning a light emitting device so as to emit light through a blood sample;

- 1 (b) energizing the light emitting device such
that light is emitted through the blood sample;
- 5 (c) positioning a first light detecting device
such that the first light detecting device receives
back-scattered light from light emitted from the light
emitting device through the blood sample along a first
path;
- 10 (d) positioning a second light detecting device
such that it receives back-scattered light from light
emitted from the light emitting device into the blood
sample along a second path, whereby the light emitting
device, the first light detecting device, and the
second light detecting device are all positioned in a
predetermined geometric relationship, and whereby the
second path is longer than the first path;
- 15 (e) providing a feedback circuit for monitoring
the light detected by the first light detecting
device;
- 20 (f) regulating the intensity of light emitted by
the light emitting device so that the amount of light
detected by the first light detecting device remains
at a constant value; and
- 25 (g) detecting the amount of light received by
the second light detecting device.
24. A method for measuring the hematocrit of blood as
defined in claim 23, further comprising the step of
providing an amplifier which receives and converts signals
from the light detecting devices so as to generate an
amplification signal which is a simple linear
representation of the hematocrit of blood in the blood
sample.
- 35 25. An apparatus for regulating the operation of a
plasma separator apparatus to keep the hematocrit

1 measurement of blood output therefrom within a predetermined range, comprising:

5 a plasma separator apparatus for removing unwanted waste components from the blood in order to cleanse the blood; and

10 monitoring means for measuring the hematocrit of the cleansed blood outputted from the plasma separator apparatus, and for thereafter automatically regulating operating parameters of the plasma separator apparatus so as to maintain a hematocrit of the blood within a predetermined range.

26. An apparatus as defined in claim 25 wherein said plasma separator apparatus comprises separating means for separating plasma from the cellular components of blood and washing means for further cleansing of the blood.

27. An apparatus as defined in claim 25, wherein the monitoring means for automatically regulating operating parameters of the plasma separator apparatus comprises a hematocrit sensor for measuring the hematocrit of blood, interconnected with the plasma separator apparatus by a microcomputer, said hematocrit sensor comprising light emitting means for emitting light into a blood sample, first light detecting means for detecting light emitted from the light emitting means, said first light detecting means positioned to receive light emitted from the light emitting means into the blood sample along a first path, and the first light detecting means outputting a signal corresponding to the amount of light detected, second light detecting means for detecting light emitted from the light emitting means, said second light detecting means being positioned to receive light emitted from the light emitting means into the blood sample along a second path, such that light emitted from the light emitting means must travel

- 1 farther to reach the second detecting means than to reach
the first light detecting means, thereby forming a second
path from the light emitting means to the second light
detecting means which is longer than the first path from
5 the light emitting means to the first light detecting
means, and regulating means for regulating the intensity of
light emitted by the light emitting means such that the
received light on one of the paths remains at a constant
value.
- 10
- 28. An apparatus as defined in claim 21, wherein the monitoring means for automatically regulating operating parameters of the plasma separator apparatus comprises a hematocrit sensor for measuring the hematocrit of blood, 15 interconnected with the plasma separator apparatus by limit switches, said hematocrit sensor comprising light emitting means for emitting light into a blood sample, first light detecting means for detecting light emitted from the light emitting means, said first light detecting means positioned to receive light emitted from the light emitting means into the blood sample to the first light detecting means along a first path, and the first light detecting means outputting a signal corresponding to the amount of light detected, second light detecting means for 20 detecting light emitted from the light emitting means, said second light detecting means being positioned to receive light emitted from the light emitting means into the blood sample to the second light detecting means along a second path, such that light emitted from the light emitting means 25 must travel farther to reach the second detecting means than to reach the first light detecting means, thereby forming a second path from the light emitting means to the second light detecting means which is longer than the first path from the light emitting means to the first light detecting means, and regulating means for regulating the 30
- 35

1 intensity of light emitted by the light emitting means such
that the received light on one of the paths remains at a
constant value.

5 29. A method for controlling the operation of a
plasma separator apparatus by use of hematocrit measurement
comprising the steps of:

10 (a) attaching a hematocrit sensor to a plasma
separator apparatus wherein cellular components of
blood, red blood cells, white blood cells, and
platelets, are separated from waste components such as
plasma, anticoagulant, toxins, and other relatively
small molecules, said hematocrit sensor being capable
of measuring the hematocrit level in blood;

15 (b) adjusting at least one operating parameter
of the plasma separator apparatus in order to maintain
the hematocrit within a predetermined range.

20 30. A method as defined in claim 29, wherein the step
of adjusting at least one operating parameter of the plasma
separator comprises joining the hematocrit sensor to the
plasma separator apparatus by a microprocessor wherein
various algorithms are programmed such that each hematocrit
reading automatically produces a different and appropriate
25 response from the plasma separator apparatus.

31. An optical connector for use with a hematocrit
sensor comprising:

30 a generally hollow member adapted to receive a
blood sample therein with respect to which hematocrit
is to be measured; and

 an optically clear flexible optical window
positioned on the generally hollow member, and through
which the blood sample within the generally hollow

1 member may be visually accessed for measurement of its
hematocrit.

5 32. An optical connector as defined in claim 31,
wherein the flexible optical window comprises a
polyvinylchloride resin material.

10 33. An apparatus for measuring the hematocrit of
blood as defined in claim 31, further comprising a support
extending from the flexible optical window substantially
perpendicularly from the generally hollow member for
securing to the cylindrical member a hematocrit sensor so
as to allow measurement of the hematocrit of the blood
sample within the generally hollow member.

15

20

25

30

35

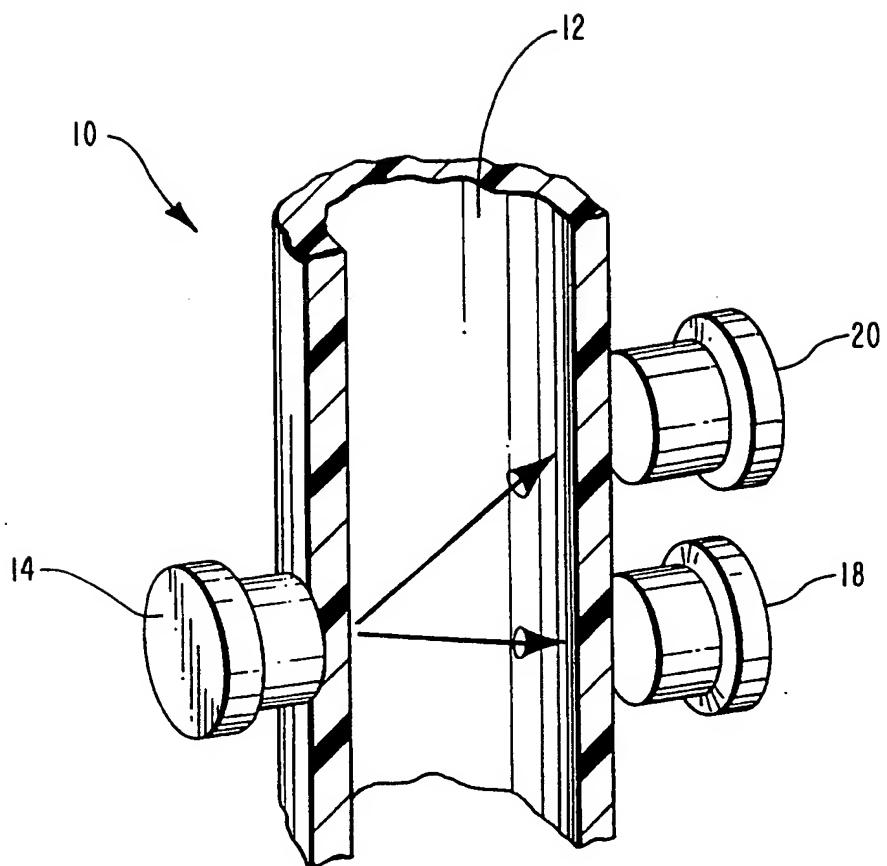


FIG. 1

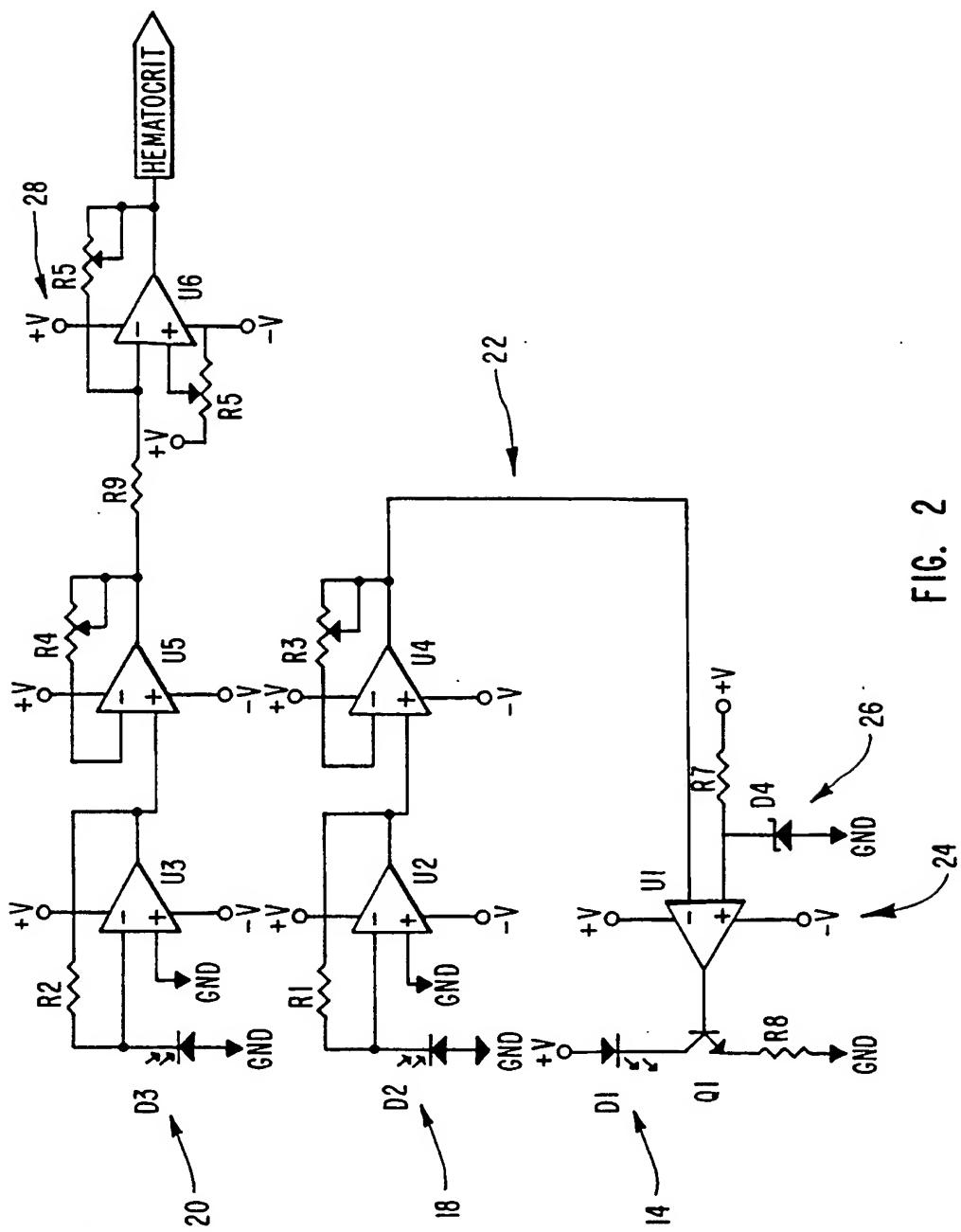


FIG. 2

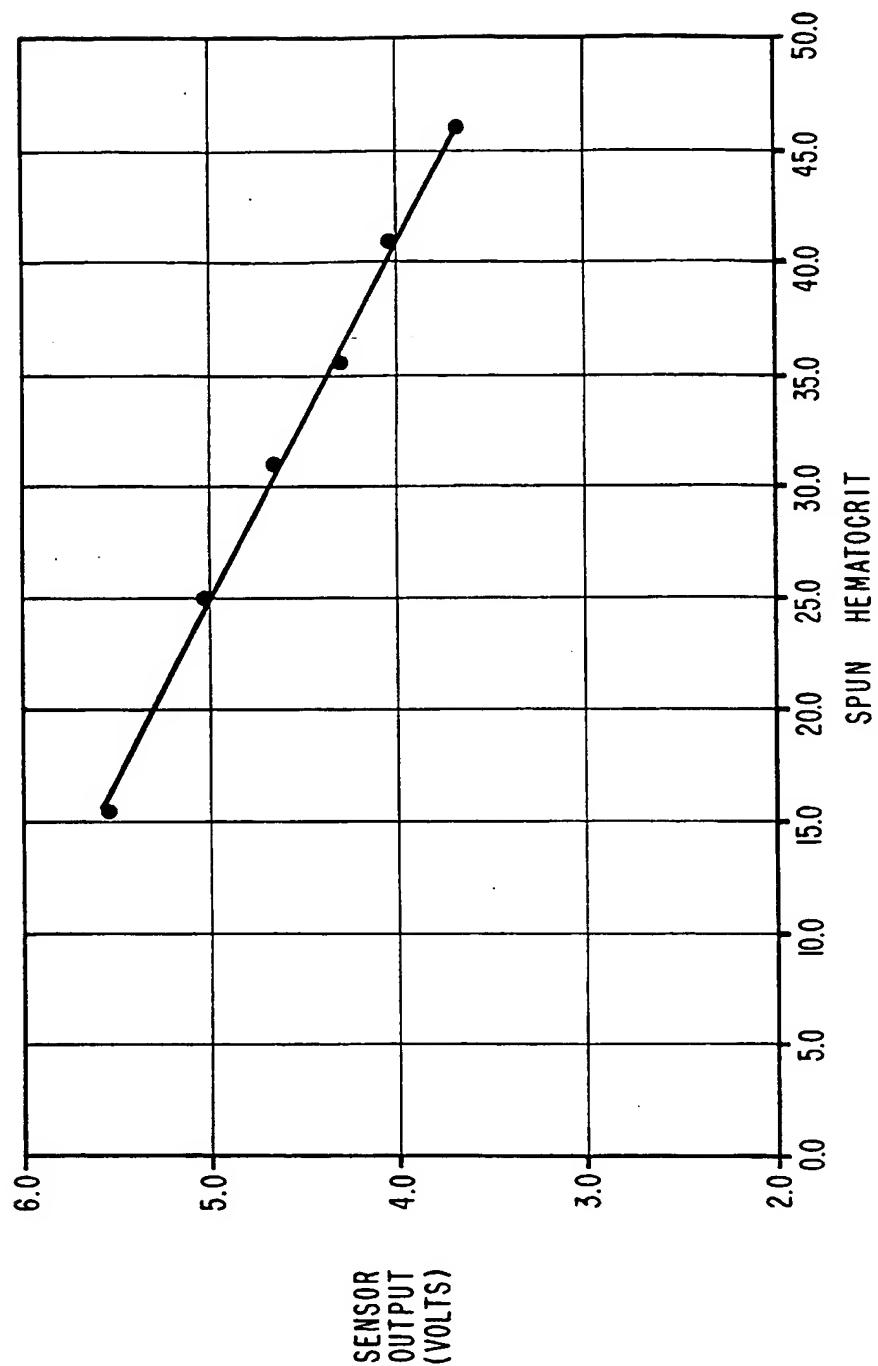


FIG. 3

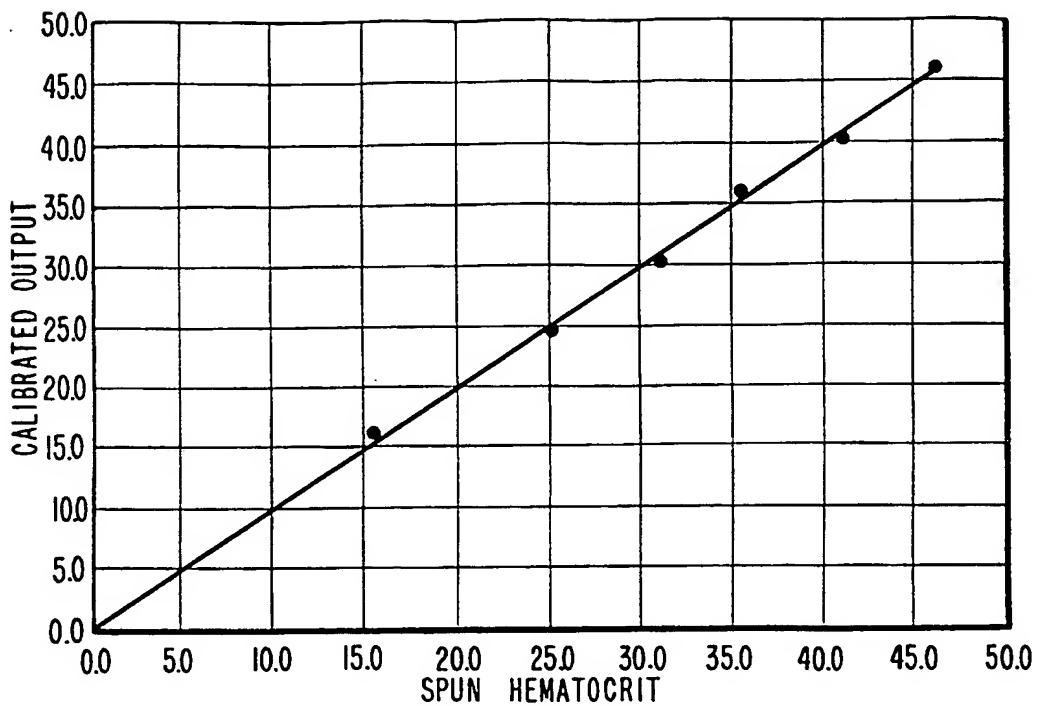


FIG. 4

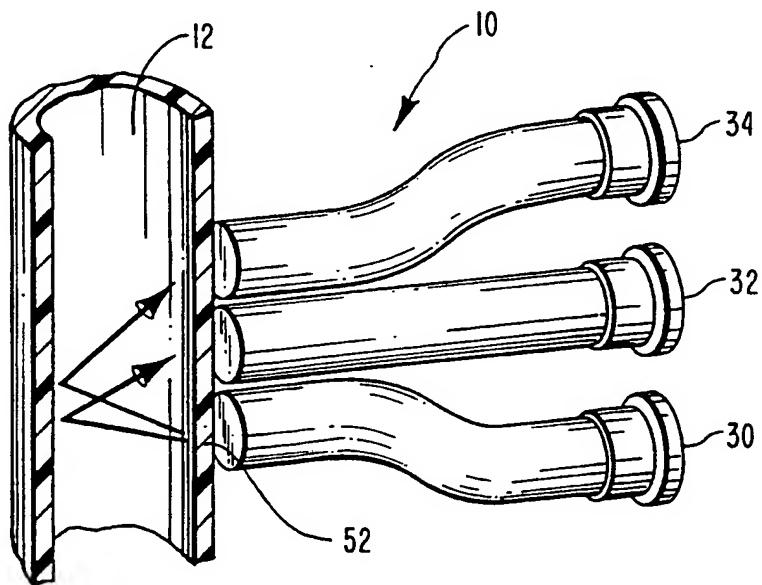


FIG. 5

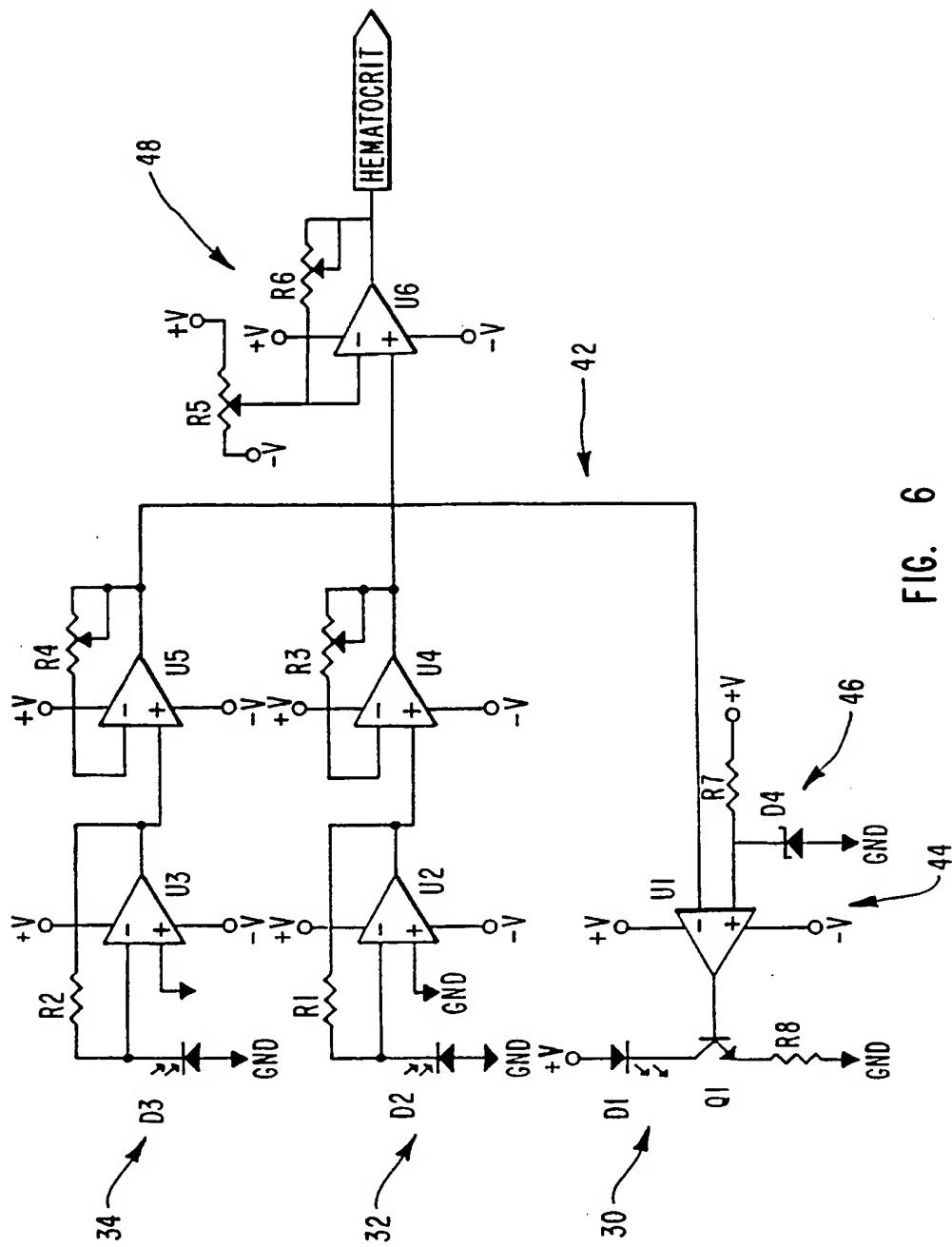


FIG. 6

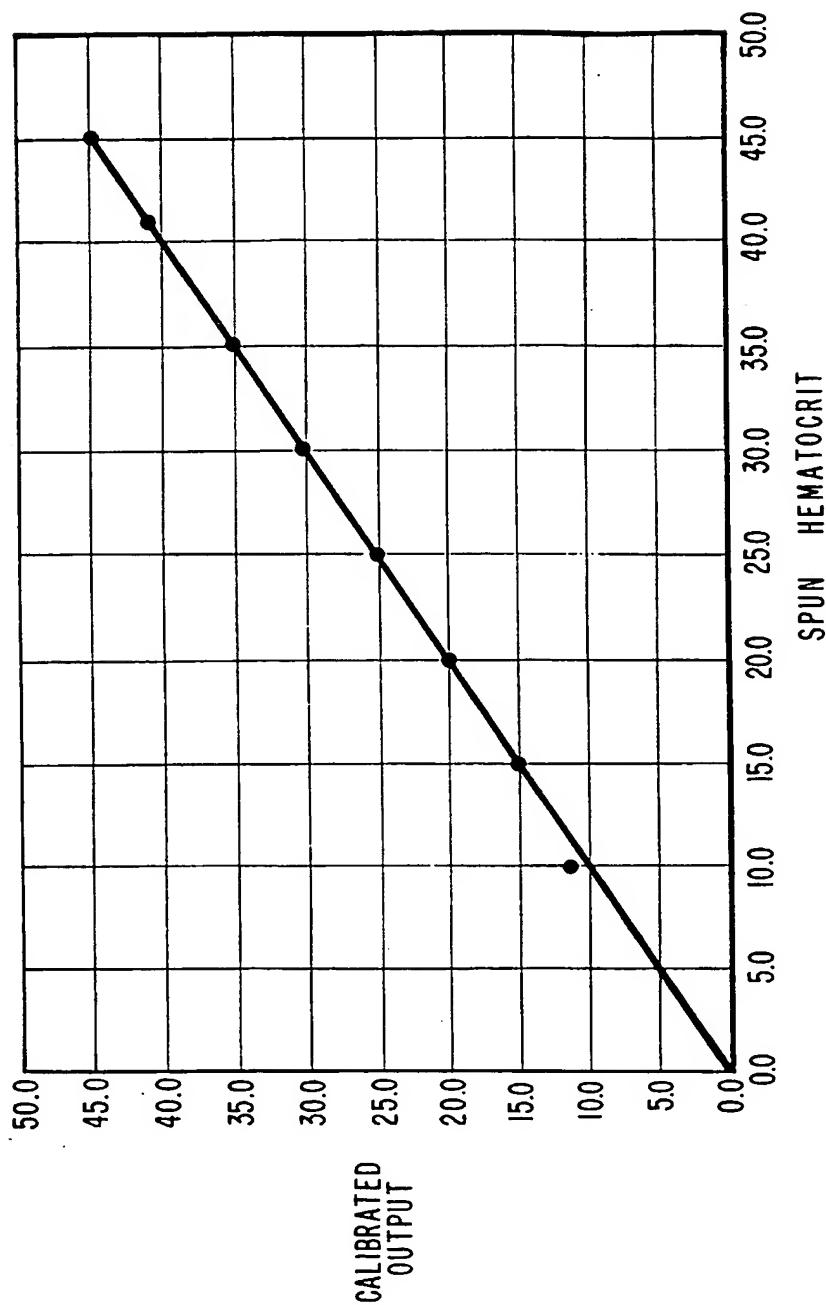


FIG. 7

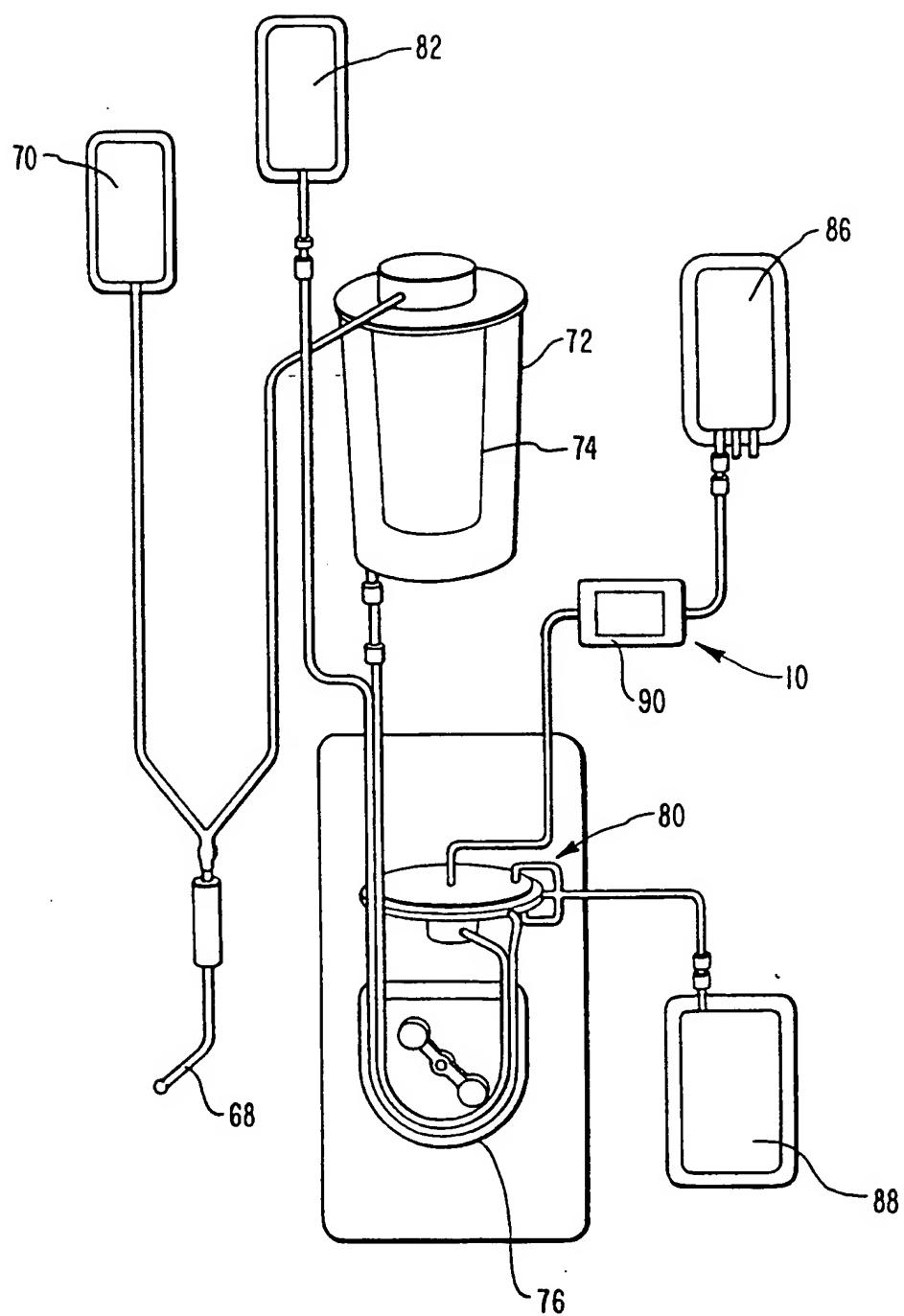


FIG. 8

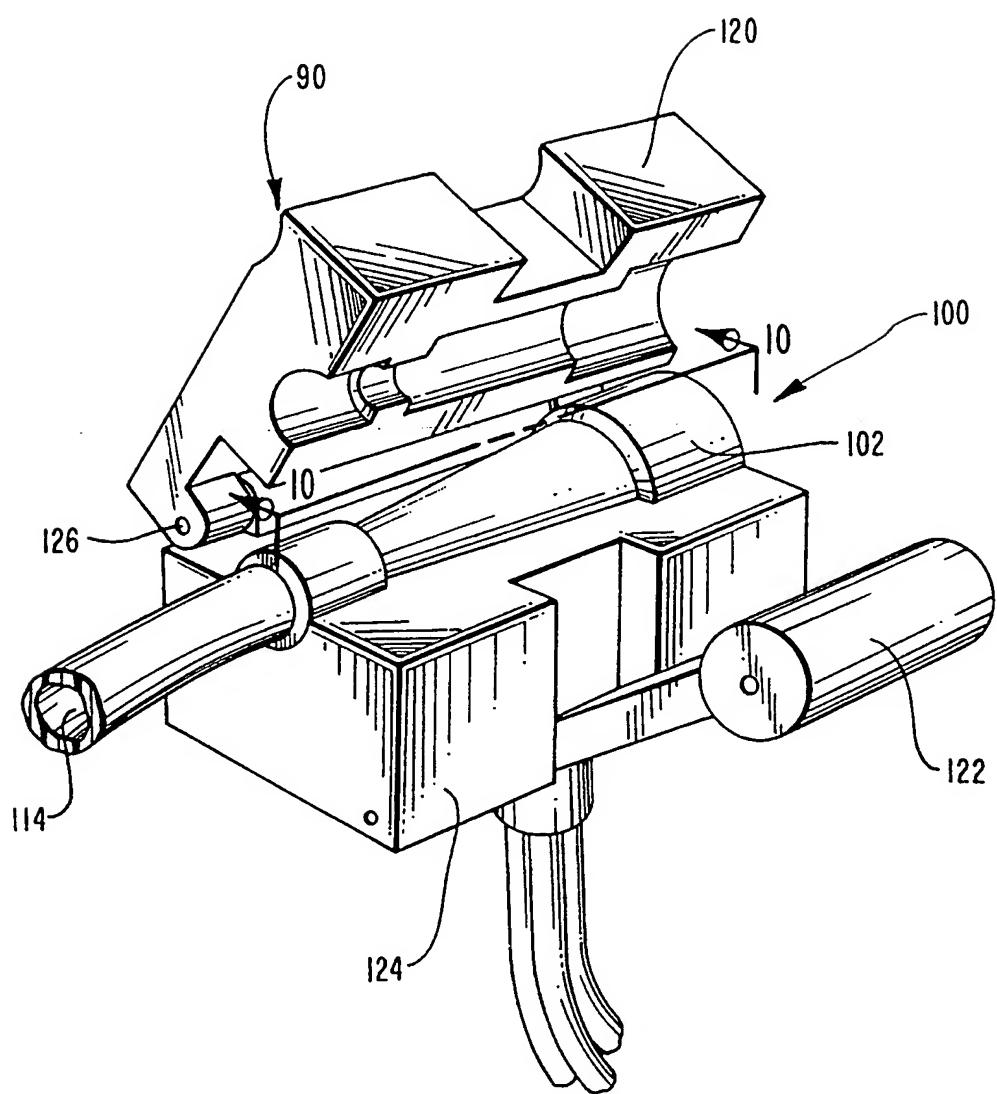


FIG. 9

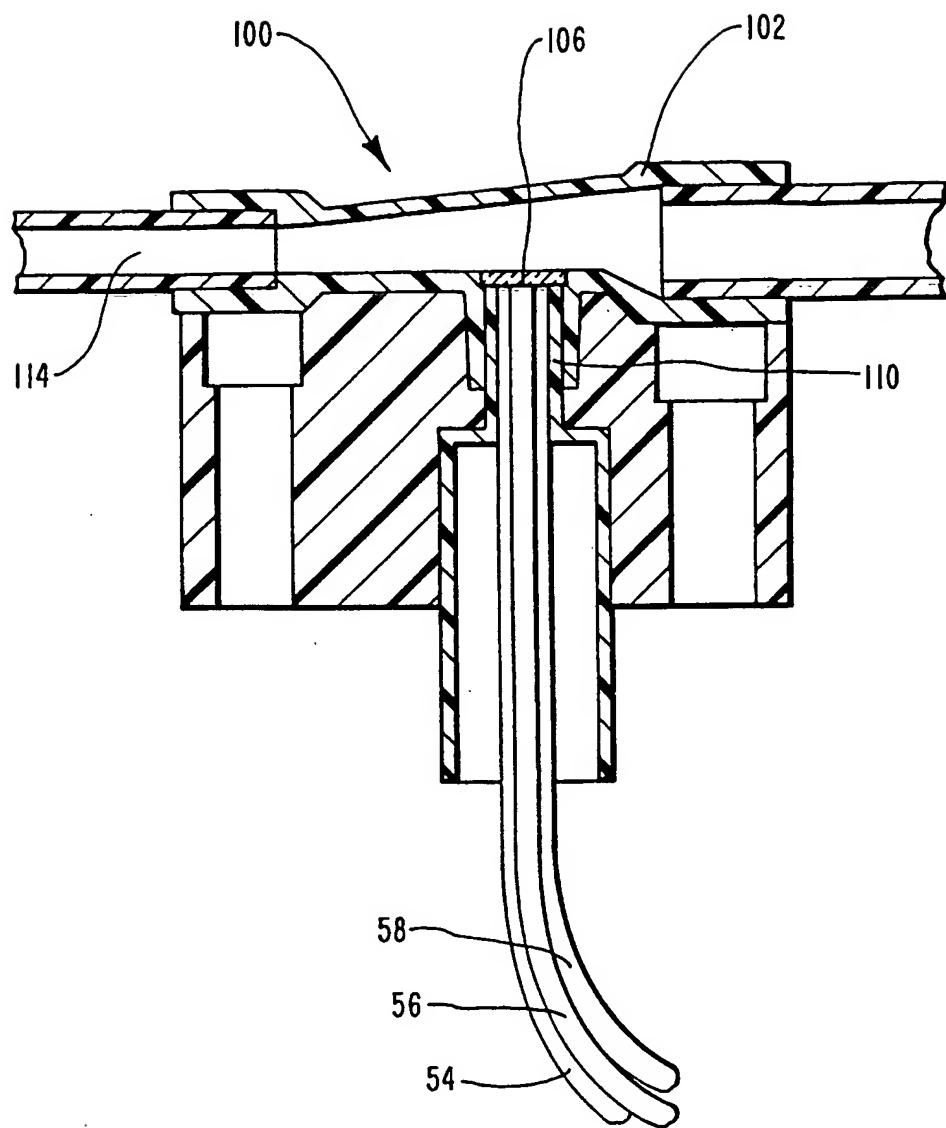


FIG. 10



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 5/00		A3	(11) International Publication Number: WO 94/01749 (43) International Publication Date: 20 January 1994 (20.01.94)
<p>(21) International Application Number: PCT/US93/06057 (22) International Filing Date: 24 June 1993 (24.06.93) (30) Priority data: 07/906,926 30 June 1992 (30.06.92) US</p> <p>(71) Applicant: ADVANCED HAEMOTECHNOLOGIES [US/US]; 2828 North Crescent Ridge Drive, The Woodlands, TX 77381 (US).</p> <p>(72) Inventor: MAYNARD, David, L. ; 18 Ridgeline Court, The Woodlands, TX 77381 (US).</p> <p>(74) Agents: SEELEY, David, O. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).</p>		<p>(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 14 April 1994 (14.04.94)</p>	
<p>(54) Title: APPARATUS AND METHODS FOR MONITORING HEMATOCRIT LEVELS OF BLOOD</p>			
<p>(57) Abstract</p> <p>An apparatus and method are provided for measuring the hematocrit level of blood. The presently preferred embodiment comprises a light emitting device (14) which emits an amount of light into a blood sample (12). This light travels through the blood sample to two light detecting devices (18, 20) positioned relative to the light emitting device in a predetermined geometry such that light must travel farther to reach one of the light detecting devices than to reach the other. According to the present invention, the amount of light detected by one of the light detecting devices (18, 20) is regulated so that the amount of light detected is constant. Thereafter, the amount of light detected by the unregulated light detecting device is a linear representation of the hematocrit of the blood in the blood sample. The hematocrit sensor may be used to regulate the operating parameters of an autotransfusion system to maintain the hematocrit of the blood within a predetermined range.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/06057

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 5/00

US CL : 128/633

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/632-634; 150/338.1, 345; 356/39-41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US, A, 4,417,812, (Cserey et al.), 29 November 1983. See entire document.	1,6,7 ----- 1-5,8-24,27
Y		
X ---	US, A, 4,444,498, (Heinemann), 24 April 1984. See entire document.	31-33 ----- 2-28
Y		
Y, P	US, A, 5,178,603, (Prince), 12 January 1993. See entire document.	25-28

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* "A" document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* "E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
* "O" document referring to an oral disclosure, use, exhibition or other means		
* "P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

04 MARCH 1994

Date of mailing of the international search report

09 MAR 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

SAMUEL RIMELL

Telephone No. (703) 308-2677